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EXAMINER	
FLOOD, MICHELE C	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/827,371	HUNG, DAVID	
	Examiner	Art Unit	
	Michele C. Flood	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 6-33* is/are pending in the application.

4a) Of the above claim(s) *12-21 and 28-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,6-11 and 22-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed by Applicant on December 29, 2003.

The claims have been examined, insofar, as they read on the elected invention, namely "a nonabsorbable biocompatible solution" .

Claims 1, 6-11 and 22-27 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Claim Rejections - 35 USC § 112

Claims 1, 6-11 and 22-27 as amended remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection stands for the reasons set forth in the previous Office action and for the reasons set forth below.

Applicant argues " that functional features are implicit in the term 'nonabsorbable biocompatible solution' to enable one skilled in the art to which it pertains to make and/or use the invention, as required by section 112, first paragraph [citation omitted]". Applicant further argues case law. However, Applicant's arguments are not persuasive because the Examiner's preliminary analysis and extensive search demonstrates that the claimed subject matter cannot be adequately searched by class or keyword among patents and typical sources of non-patent literature. Hence, the term 'nonabsorbable

biocompatible solution' is unsearchable. Therefore, the Office maintains the following as set forth in the previous Office action:

The specification lacks adequate written description for the claimed invention in view of the following points in accordance with the written description requirements of 35 U.S.C. 112:

The description must clearly allow persons of ordinary skill in the art to recognize what is claimed. Thus, an applicant must comply with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of the ingredients requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984). Accordingly, describing a method of treatment comprising the administration of material generally known to exist, in the absence of knowledge as to what that material consists of is not a description of that material or the method of use thereof. In the instant case, on page 5, line 29 to page 6, line 11 of the specification, Applicant discloses the intraductal administration of a wash fluid comprising a biocompatible agent or solution, *e.g.*, a nonabsorbable fluid. The specification further discloses on page 6, lines 30 to page 7, lines 1-2, the advantages of using a nonabsorbable fluid in the instantly claimed

method of treatment. However, other than the mere mention on page 6, lines 22-24, that "the invention provides administering a nonabsorbable fluid or a fluid that actually draws fluid to it, *e.g.,* an oncotic or osmotic fluid in the process of collecting fluid from the duct", Applicant fails to adequately describe as to what Applicant defines or considers as a "nonabsorbable biocompatible solution". For example, nowhere in the present specification does Applicant render a definition of the term "nonabsorbable biocompatible solution" or cite an example of the term thereof.

Thus, Claims 1, 6-11 and 22-27 as amended remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The broad generic claim lacks sufficient description to inform a skilled artisan that Applicant was in possession of the claimed invention at the time of filing since the specification lacks a sufficient number of species which have been described by complete structure or identifying characteristics, thus the description requirement has not been satisfied, see Eli Lilly, 119 F. 3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1977).

Claims 1, 6-11 and 22-27 as amended remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection stands for the reasons set forth in the previous Office action and for the reasons set forth below.

Applicant argues that the term 'nonabsorbable compatible solution' is clear and definite, in view of the specification and the knowledge available at the time of the invention. However, Applicant's arguments are not persuasive for the reasons set forth immediately above, *i.e.,* an intensive search on the term by the Examiner in both patent and non-patent literature did not uncover either the meaning or any examples of the term. Thus, the metes and bounds of Claim 1 as amended remain uncertain by the term "nonabsorbable compatible solution" because it is unclear as to the subject matter Applicant intends to direct the subject matter of the claimed invention. Moreover, it is uncertain as to how one of ordinary skill in the art would not know how to interpret the metes and bounds of this limitation, since neither the claims nor the specification defines or apprises the meaning of the term, contrary to the assertion that the term 'nonabsorbable compatible solution' is axiomatic. The lack of clarity renders the claim very vague and very ambiguous.

Applicant argues that the limitations of Claim 7 are not outside the scope of the recited Markush group because Claim 7 properly and clearly defines a functional characteristic of a solution that may be applicable to a number of the members recited in the Markush group of Claim 1. While Applicant's argument is directed to all of the members comprising the Markush of Claim 1, Applicant is reminded that the claims have been examined, insofar, as they read on the elected invention, namely "nonabsorbable compatible solution"; and, while the disputable phrase may be applicable to a number of the members recited in the Markush group of Claim 1 (although Applicant has not pointed to which members are related to the phrase), as set forth immediately above, the term "nonabsorbable compatible solution" remains vague and ambiguous. Therefore, Claim 7 remains vague and indefinite by the phrase

"wherein the agent comprises a carbonated fluid comprising super oxygenated fluid that is colder than room temperature before administration" because it is unclear as to the subject Applicant intends to direct the invention. For instance, it appears that the claimed limitations are outside the scope of the recited Markush group of Claim 1, since it is uncertain as to whether any, if any, of the agents that increase retrievable ductal fluid from a breast duct "comprises a carbonated fluid comprising super oxygenated fluid that is colder than room temperature before administration".

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Objections

Claims 8-11 as amended remain objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. The rejection stands for the reasons set forth in the previous Office action and for the reasons set forth below.

Applicant 's argument is directed to the idea that Claims 8-11 limit the scope of Claim 1 by requiring the additional steps of collecting or analyzing the ductal fluid sample obtained through the method described in Claim 1. Applicant further argues, "Claim 1 does not positively recite these specific steps." As well pointed out by Applicant, Claim 1 does not recite the steps of either collecting or analyzing the ductal fluid sample obtained through the method described in Claim 1. Applicant is reminded that the invention of Claim 1 is directed to a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast of a duct of a patient comprising the intraductal administration of an agent that increases retrievable ductal fluid from a breast duct. Nowhere in the recitation of Claim 1 is there any limitation for obtaining retrievable fluid in a breast duct of a patient. The only limitation that Claim 1 requires is a step for preparing for intraductal retrieval or fluid, cells and/or other material from a breast of a duct of a patient. Nowhere is there a limitation for obtaining any increased retrievable from a breast duct of a patient. Thus, Applicant's arguments are not persuasive because Claims 8-11 fail to further the subject matter of independent Claim 1, *i.e.*, a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient, because the claimed invention is a one-step process, whereas the claimed process steps of Claims 8-11 are directed to post-processing steps not required by Claim 1, since no retrievable fluid *per se* is obtained in the process step of Claim 1.

Claim Rejections - 35 USC § 102

Claims 1, 8, 10, 22, 25 and 27 as amended remain rejected under 35 U.S.C. 102(b) as being anticipated by Falconer et al. (U), as evidenced by the teachings of

Kartinos et al. (B) and Mullins (C). The rejection stands for the reasons set forth in the previous Office and for the reasons set forth below.

Applicant argues that Falconer fails to anticipate the claimed subject matter because the method taught by Falconer discloses an increase in water content of the surrounding alveolar tissue. However, Applicant's arguments are not persuasive because on page 182, Column 2, lines 6-15, Falconer teaches a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally to the patient prolactin (a growth hormone), ouabain or both dissolved in a solution of [Na+], [K+] and [Cl-] containing Dextran Blue 2000 (a nonabsorbable biocompatible solution, as evidenced by the teachings of Kartinos and Mullins). Falconer further teaches removing and sampling alveolar tissue associated with the injected duct systems for water content determinations and Na+, K+ and Cl- and [14C]-lactose analysis, on page 184, Column 2, lines 29-33. In Table 1, Falconer shows that increasing the amounts of prolactin increased the water content of wet tissue in the treated mammary gland tissue. On page 184, Column 1, lines 13-19 bridging Column 2, lines 1-6, Falconer teaches *in vivo* intraductal injection of prolactin to a patient showed an increase [K+] of 10 mmol/kg wet tissue (see Table 3); whereas, *in vivo* intraductal administration of prolactin and ouabain an increase [Na+]. On page 182, Column 2, lines 14-19, Falconer teaches an increased extracellular water content of the ouabain-treated glands (*see* Table 3). Table 3 also shows an increased extracellular water content of the prolactin-treated glands, as well.

Falconer does not expressly teach his method for the intraductal administration of prolactin (a growth hormone), ouabain or both dissolved in a solution of [Na+], [K+] and [Cl-] containing Dextran Blue 2000 (a nonabsorbable biocompatible solution) to a

patient as a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast of a patient comprising administering intraductally to the patient an agent that increases retrievable ductal fluid from a breast duct, wherein the agent is a nonabsorbable biocompatible solution. However, the method taught by Falconer is a one step process comprising the intraductal administration of the same ingredient, as disclosed by Applicant. Thus, a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally to the patient an agent that increases retrievable secreted ductal fluid, wherein the agent is a nonabsorbable biocompatible solution, from a breast duct is inherent to the method of treatment taught by Falconer.

The reference anticipates the claimed subject matter.

Claims 1, 6, 8, 10, 22, 25 and 27 as amended remain rejected under 35 U.S.C. 102(b) as being anticipated by Martyn et al. (V), as evidenced by the teachings of Kartinos et al. (B) and Mullins (C). The rejection stands forth in the previous Office action and for the reasons set forth below.

Applicant argues that Martyn fails to anticipate the claimed subject matter because the method taught by Martyn "describes an *in vivo* experiment in rabbits to measure the effect of prolactin and progesterone on lipogenic-enzyme activity and glycerolipid synthesis." Applicant further argues, "In fact, as evidenced on page 326, Column 1, lines 28-41, as well as Table 4 on page 326, Blue Dextran mixed with Phosphate-buffered saline had no effect on fatty acid synthesis." However, Applicant's arguments are not persuasive because Martyn teaches a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient

comprising administering intraductally to the patient prolactin as either an emulsion or an aqueous solution, made by dissolving prolactin in NaOH and diluting with phosphate buffered saline containing Blue Dextran (a nonabsorbable biocompatible solution, as evidenced by the teachings of Kartinos and Mullins). The emulsion was prepared by sonicating an aqueous solution phase consisting of phosphate buffer saline containing bovine serum albumin and Blue Dextran with safflower oil (see page 323. Column 2, under *"Mammary intraductal injections"*. In Table 1, Martyn shows that glycerolipid synthesis in the mammary gland was significantly enhanced in the presence of insulin, corticosterone and prolactin; addition of prolactin stimulated acetyl-CoA carboxylase activity; prolactin together with insulin and corticosterone stimulated activity of fatty acid synthetase; glucose-6-phosphate dehydrogenase was enhanced with prolactin injection. On page 326, Column 1, lines 9-27, Martyn teaches that intraductal injection of prolactin, or prolactin plus progesterone, had more secretion than did untreated emulsion treated or progesterone-treated glands within the same patient.

Martyn does not expressly teach his method for the intraductal administration of prolactin as either an emulsion or an aqueous solution, made by dissolving prolactin in NaOH and diluting with phosphate buffered saline containing Blue Dextran (a nonabsorbable biocompatible solution) to a patient as a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast of a patient comprising administering intraductally to the patient an agent that increases retrievable secreted ductal fluid from a breast duct, wherein the agent is a nonabsorbable biocompatible solution. However, the method taught by Martyn is a one step process comprising the intraductal administration of the same ingredient, as disclosed by Applicant. Thus, a method for preparing for intraductal retrieval of fluid, cells and/or

other material from a breast duct of a patient comprising administering intraductally to the patient an agent that increases retrievable ductal fluid, wherein the agent is a nonabsorbable biocompatible solution, from a breast duct is inherent to the method of treatment taught by Martyn.

The reference anticipate the claimed subject matter.

Claim Rejections - 35 USC § 103

Claims 1, 8-11, 22 , 25 and 27 as amended remain rejected under 35 U.S.C. 103(a) as being unpatentable over Falconer et al. (U) in view of Love (A). The rejection stands forth in the previous Office action and for the reasons set forth below.

Applicant's arguments have been fully considered but they are not deemed persuasive because the cited references provide the suggestions and motivation to the claimed invention.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the primary reference of Falconer was relied upon for the reasons set forth above. Because Falconer teaches the claimed method except for wherein collecting comprises

accessing a breast duct with a device and withdrawing a portion of the increased retrievable secreted ductal fluid into the device and wherein the step of analyzing comprises identifying a marker of a breast condition, the secondary reference of Love was relied upon because Love the intraductal administration of physiological saline to a breast duct for the retrieval of fluid, cells and/or other material from a breast of a patient. In Column 6, lines 55-67, Love discloses that "The volume of fluid introduced into the ductal network D_2 will be sufficiently large so that substantially the entire volume of the ductal network may be filled with the washing fluid and excess fluid will flow from the network as it is displaced by additional fluid input . . . The remaining fluid will continue to be introduced and will thus flush the cellular and other marker materials from the ductal network into the opening . . ." After collection of the washing fluid comprising the retrievable fluid obtained from the breast duct through a double lumen catheter, Love teaches analyzing the fluid to identify a marker of a breast condition (see Column 5, lines 38-44).

Thus, with Falconer providing the motivation to intraductally administer a nonabsorbable biocompatible solution to prepare for the intraductal retrieval of fluid, cells and/or other materials from a breast duct from a patient, and with Love teaching a that although physiological saline is a preferred washing fluid, other physiologically solutions such as the contrast media, *i.e.,* Dextran Blue, taught by Falconer may also be used, one of ordinary skill in the art would have been obvious to one of ordinary skill in the art at the time the invention was made to add the instantly claimed process step to the method taught by Falconer to provide the claimed invention. Moreover, at the time

the invention was made, one of ordinary skill in the art would have been motivated and one would have had a high expectation of success to add the process steps taught by Love to the method of treatment taught by Falconer to provide the claimed method because in Column 2, lines 21-32 and Column 3, lines 5-20, Love suggests that her method for obtaining fluids, marker substances and cellular material comprising the intraductal administration of fluids into the breast of a patient is minimally traumatic to the patient and provides a reliable and consistent method of obtaining cellular and non-cellular marker materials from the ductal networks in a breast to enable screening, diagnosis, and monitoring of disease conditions of the breasts. *See* Column 3, lines 22-65. Thus, at the time the invention was one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the claimed process step of accessing a breast duct with a device and withdrawing a portion of the increased retrievable secreted ductal fluid into the device and the process step of analyzing comprises identifying a marker of a breast condition to the method taught by Falconer to provide the claimed invention. Therefore, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the absence of evidence to the contrary.

Claims 1, 6, 8-11, 22 and 25 as amended remains rejected under 35 U.S.C. 103(a) as being unpatentable over Martyn et al. (V) in view of Love (A). The rejection stands forth in the previous Office action and for the reasons set forth below.

Applicant's arguments have been fully considered but they are not deemed persuasive because the cited references provide the suggestions and motivation to the claimed invention.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the primary reference of Martyn was relied upon for the reasons set forth above. Because Martyn teaches the claimed method except for wherein collecting comprises accessing a breast duct with a device and withdrawing a portion of the increased retrievable secreted ductal fluid into the device and wherein the step of analyzing comprises identifying a marker of a breast condition, the secondary reference of Love was relied upon because Love the intraductal administration of physiological saline to a breast duct for the retrieval of fluid, cells and/or other material from a breast of a patient. In Column 6, lines 55-67, Love discloses that "The volume of fluid introduced into the ductal network D_2 will be sufficiently large so that substantially the entire volume of the ductal network may be filled with the washing fluid and excess fluid will flow from the network as it is displaced by additional fluid input . . . The remaining fluid will continue to be introduced and will thus flush the cellular and other marker materials from the ductal network into

the opening . . ." After collection of the washing fluid comprising the retrievable fluid obtained from the breast duct through a double lumen catheter, Love teaches analyzing the fluid to identify a marker of a breast condition (see Column 5, lines 38-44).

Thus, with Martyn providing the motivation to intraductally administer a nonabsorbable biocompatible solution to prepare for the intraductal retrieval of fluid, cells and/or other materials from a breast duct from a patient, and with Love teaching a that although physiological saline is a preferred washing fluid, other physiologically solutions such as the contrast media, *i.e.,* Dextran Blue, taught by Martyn may also be used, one of ordinary skill in the art would have been obvious to one of ordinary skill in the art at the time the invention was made to add the instantly claimed process step to the method taught by Falconer to provide the claimed invention. Moreover, at the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a high expectation of success to add the process steps taught by Love to the method of treatment taught by Martyn to provide the claimed method because in Column 2, lines 21-32 and Column 3, lines 5-20, Love suggests that her method for obtaining fluids, marker substances and cellular material comprising the intraductal administration of fluids into the breast of a patient is minimally traumatic to the patient and provides a reliable and consistent method of obtaining cellular and non-cellular marker materials from the ductal networks in a breast to enable screening, diagnosis, and monitoring of disease conditions of the breasts. *See* Column 3, lines 22-65. Thus, at the time the invention was one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the

claimed process step of accessing a breast duct with a device and withdrawing a portion of the increased retrievable ductal fluid into the device and the process step of analyzing comprises identifying a marker of a breast condition to the method taught by Martyn to provide the claimed invention because also. Therefore, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 6-11 and 22-27 as amended remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 157-165 of copending Application No. 09/907,581. The rejection stands for the reasons set forth in the previous Office action and repeated below.

Applicant defers consideration of filing a terminal disclaimer until the determination of allowable subject matter by the Patent Office. Therefore, the rejection stands because: Although the conflicting claims are not identical, they are not patentably distinct from each other because the process steps, the actual ingredients, the subjects to which the ingredients are administered, and the claimed functional effect appear to be identical or essentially the same.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele C. Flood whose telephone number is (571) 272-0964. The examiner can normally be reached on 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MCF
March 11, 2004

CHRISTOPHER R. TATE
PRIMARY EXAMINER